Human Correlation Fit Testing of a Static Advanced Headform

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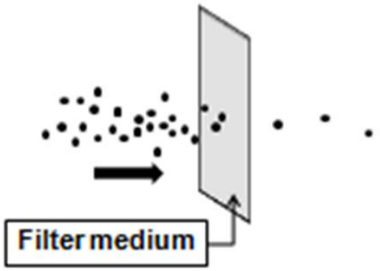
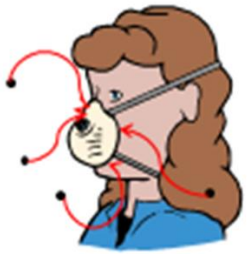
Background

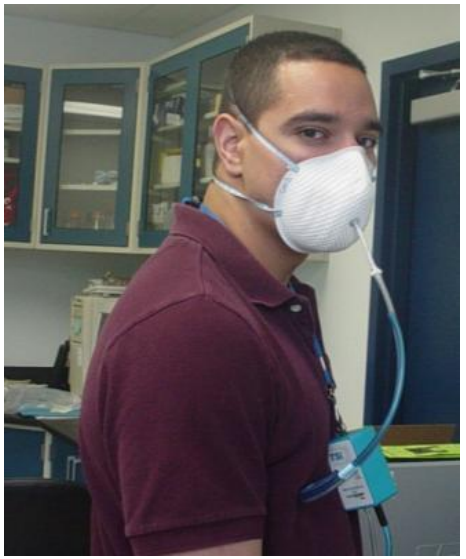
- **Since the 2009 influenza pandemic, there is increasing interest in the efficacy of respiratory protection for health care workers and emergency response personnel**
  - NIOSH-certified N95 and P100 filtering facepiece respirators (FFRs) provide expected levels of filtration performance against viable microorganisms (Wander and Heimbuch, 2009) (Balazy et.al, 2006)
  - Interest in developing an inward leakage (IL) *(combined filtration and faceseal leakage)* test system to evaluate FFRs against viable microorganisms





Background (continued)

- **Limitations of human subject testing**
  - Cannot be exposed to pathogenic microorganisms
  - High degree of variability with the same person and between persons
  - Can be difficult to find subjects of specific facial sizes to fulfill panel requirements
  - Expensive



Background (continued)

- **A collaborative study is underway to develop an IL test system using headforms that have human-like characteristics**
  - Anthropometric dimensions of current U.S. workforce
  - Skin-like surface and defined tissue depth
  - Head movements and speech
- **Bergman, Zhuang, Hanson, et al. Development of an Advanced Respirator Fit Test Headform (J. Occup. Environ. Hyg., In Press)**
  - The seven evaluated FFR models (which are expected to achieve FFs ≥ 100 on human subjects) achieved FFs ≥ 100 on the Static Advanced Headform (StAH)

Objective

- **Establish the correlation of fit of N95 Filtering Facepiece Respirators between test subjects and a Static Advanced Headform**

Test Subject

Static Advanced Headform

Benefits

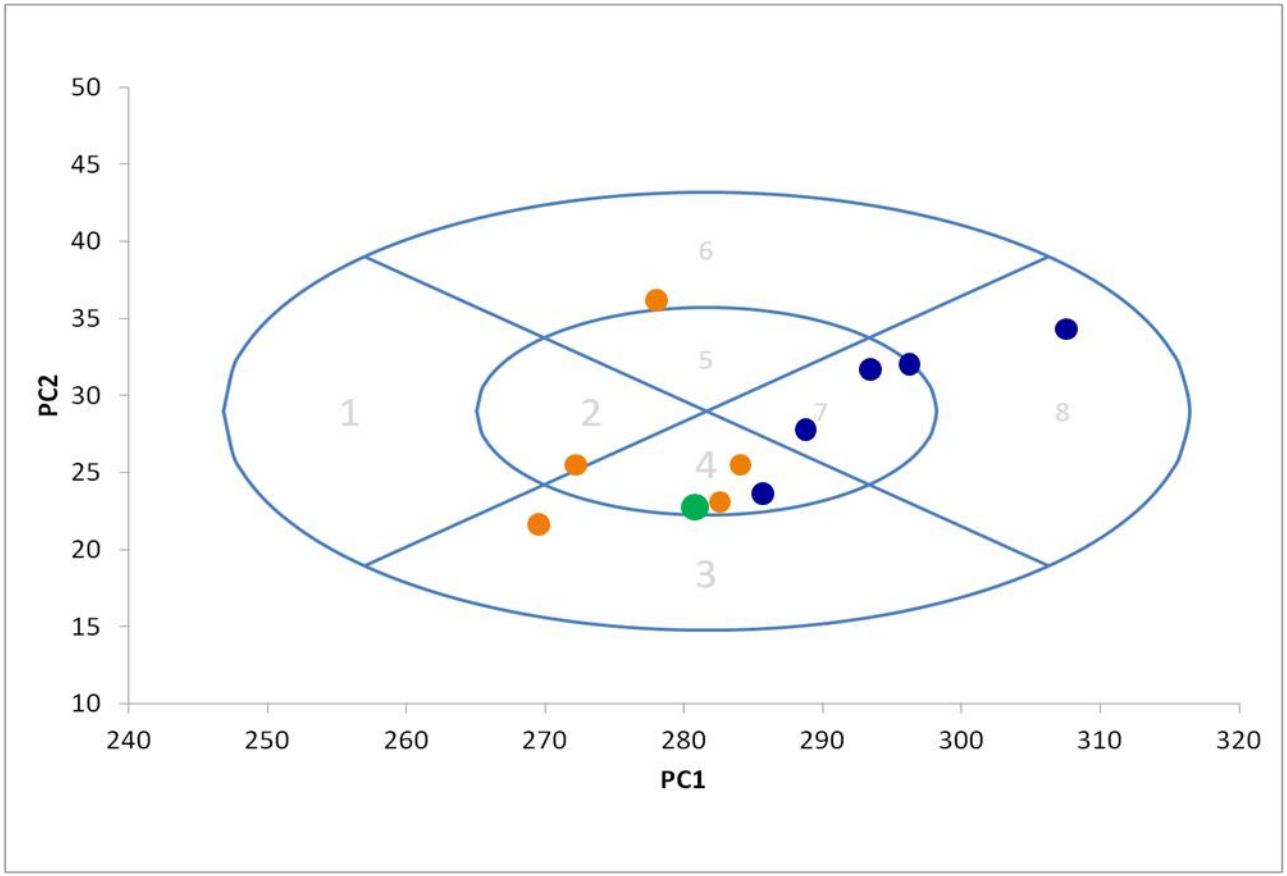
- **Establishing a good correlation of fit is a step toward implementing Advanced Headforms for:**
  - Respirator research on inward leakage (IL) of biological aerosols or inert aerosols of interest
    - Allows for IL testing where human subjects could not be used
  - Respirator design applications
  - Respirator certification / consensus standards

Methods

Variables	*n*
N95 FFR Models	8
Human Subjects	10
Visits	3
Total Fit Tests (Goal)	8 x 10 x 3 = 240

FFR Model	Size	Shape
Sperian N1105-SAF-T-FIT	M/L	Cup
Sperian N1105-SAF-T-FIT	Small	
3M 1870	One size only	Tri-fold
Kimberly–Clark PFR95-270 (46767)	Regular	Duckbill
Kimberly–Clark PFR95-270 (46867)	Small	
Moldex 1511	Small	
Moldex 1512	Medium	Cup
Moldex 1513	Large	

PCA Plot of Test Subjects



Cell	Size
1	Small
2, 4, 5, 7	Medium
8	Large
3	Short/Wide
6	Long/ Narrow

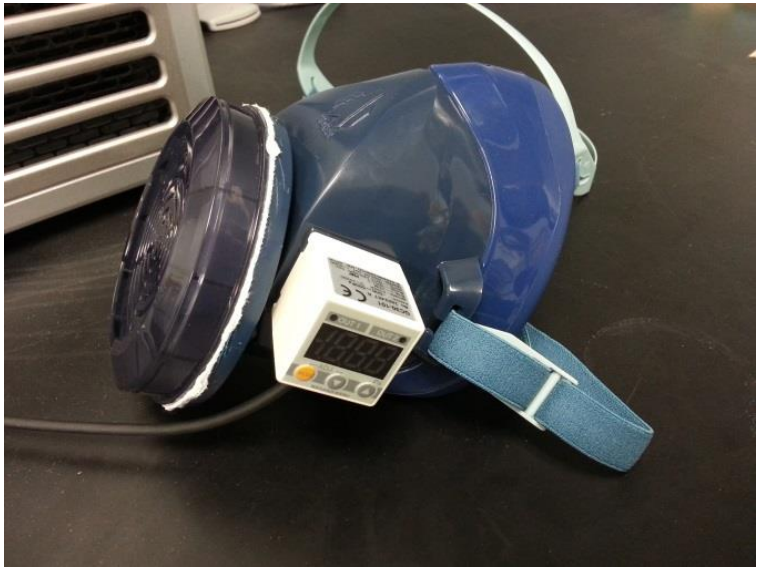
Static Advanced Headform

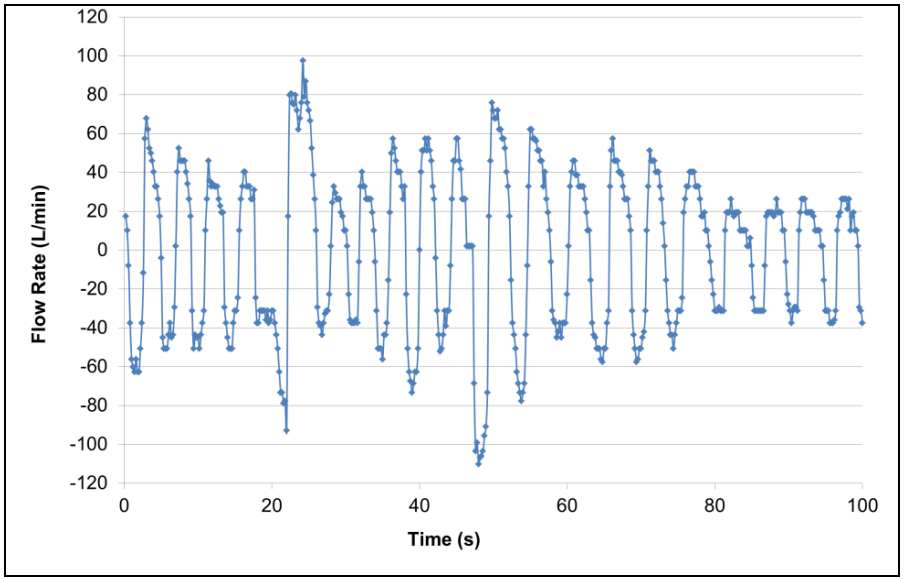
Male Subject

Female Subject

Methods (continued)

- **Breathing Pattern Recording**
  - On each visit, human subject breathing waveforms were recorded using a Koken Respiration Data Sampling System





Methods (continued)

- **Fit Testing**
  - 221 fit tests were performed by human subjects
  - The same 221 FFR samples were fit tested on the Static Headform utilizing each subject's breathing pattern
  - Each fit test is composed of three 2-minute exercises (Normal Breathing1, Deep Breathing, Normal Breathing2)

PortaCount Pro+ 8038

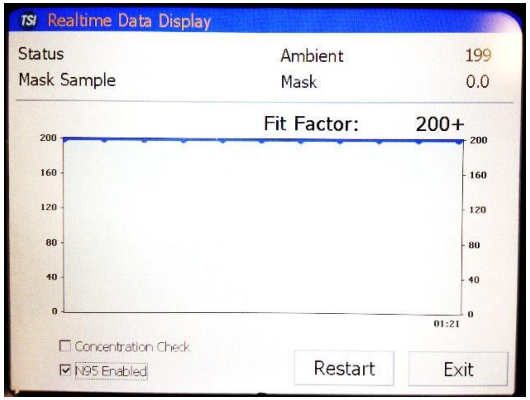
Methods (continued)

Don FFR and Perform User Seal Check (USC)

Pass USC

PortaCount "Check" Method

Realtime Fit Factor Display
(Need 10 consecutive FFs ≥ 100)



Pass "PortaCount Check"

Start Fit Test

Fail USC

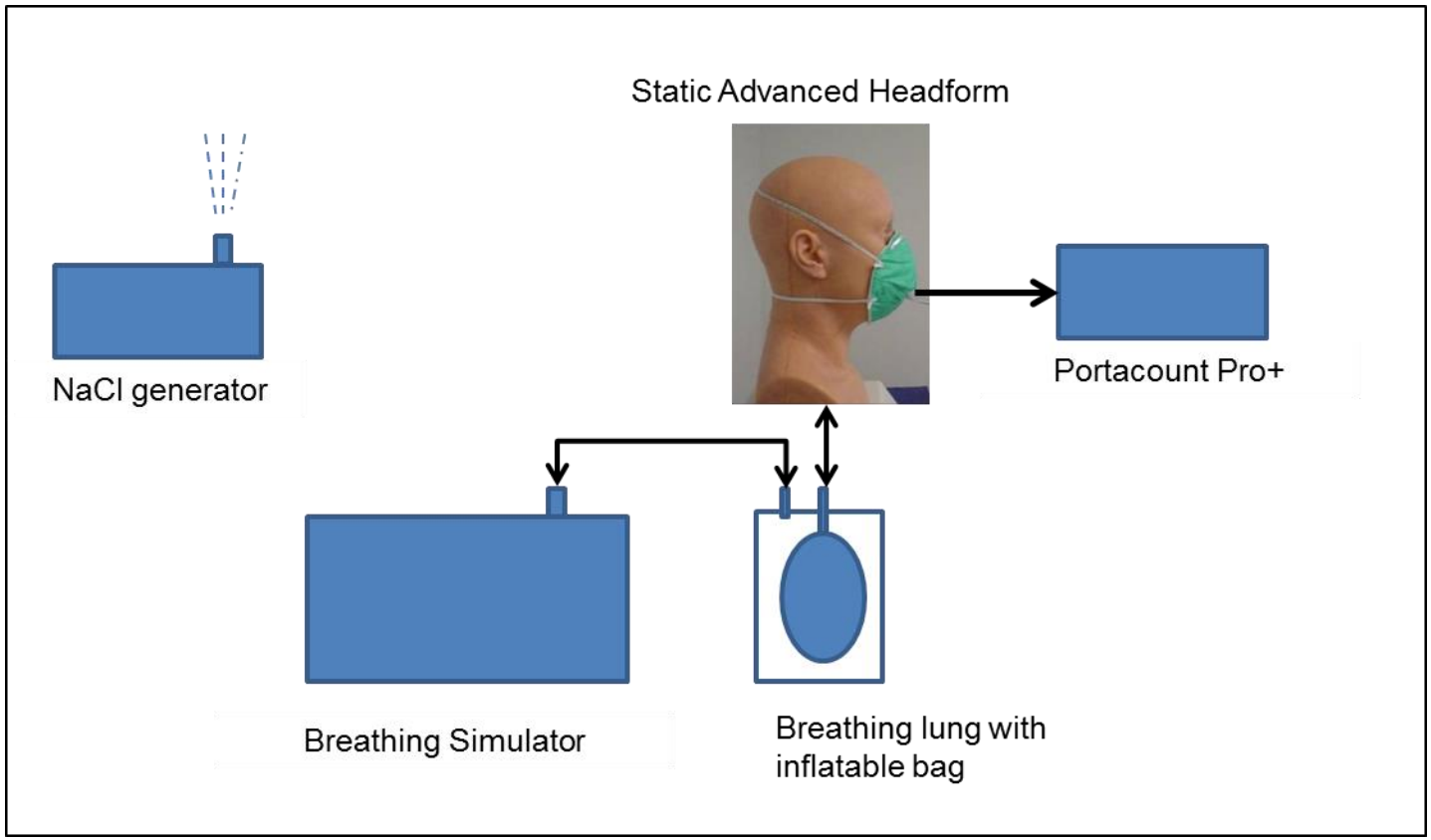
Doff, redon, and go back to USC step
(If USC Fails 3 Times, Start Fit Test)

Fail "PortaCount Check"

Doff, redon, and go back to USC step
(If "PortaCount Check" Fails 3 Times, Start Fit Test)

Methods (continued)

Headform Test Configuration



Results

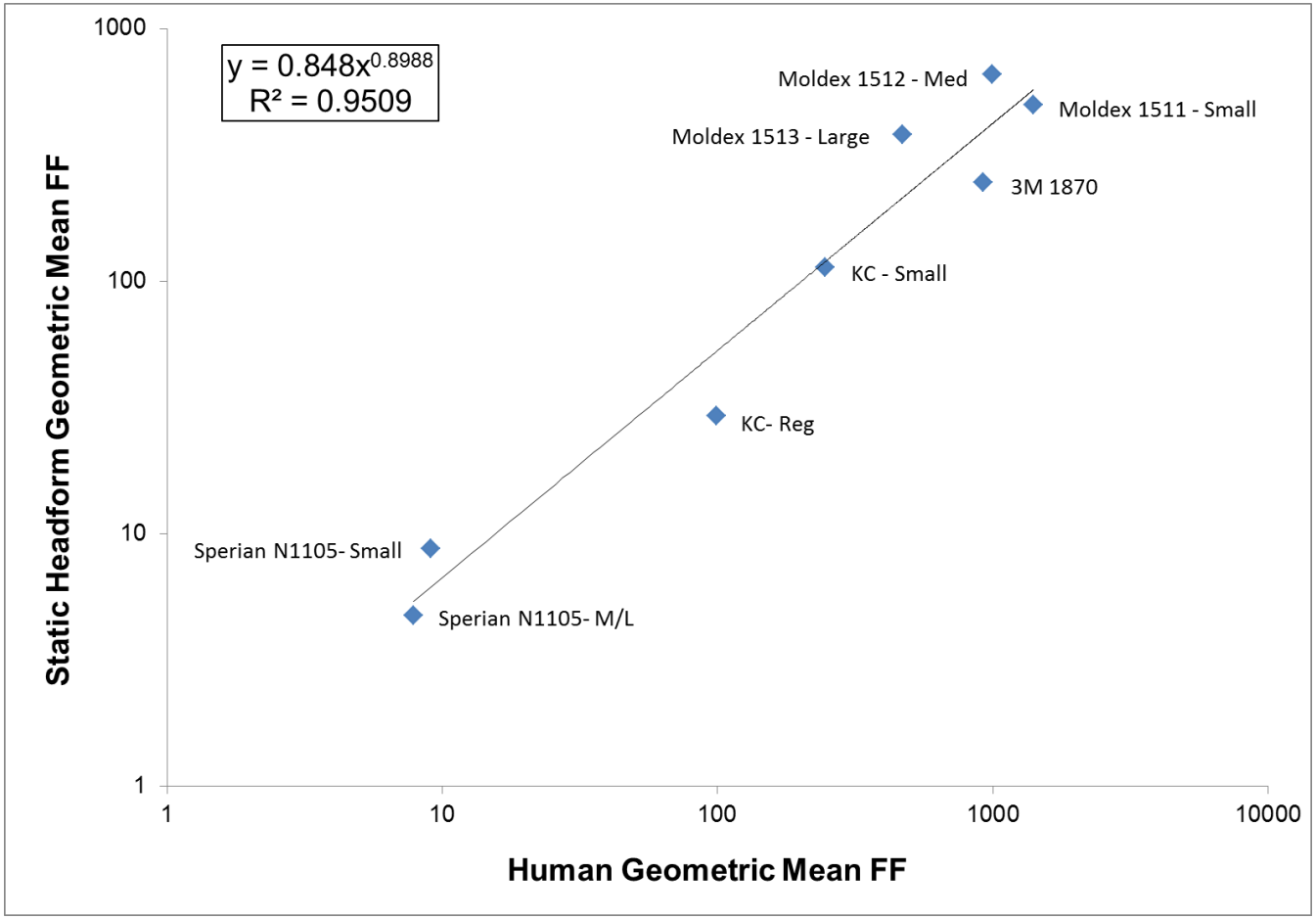
Geometric Mean "Overall" Fit Factors for Humans and Static Advanced Headform (StAH) by FFR Model

Manufacturer	Model	Size	Platform	*n**	GM FF	GSD FF	Min FF	Max FF
3M	1870	REG	Human	28	921.8**	5.0	5	8680
			StAH	28	246.2**	1.7	50	544
KC	KC-Reg	REG	Human	28	98.9**	4.0	3	586
			StAH	28	29.3**	2.3	8	241
KC	KC-S	S	Human	28	245.9**	6.3	2	5160
			StAH	28	113.6**	2.0	31	483
MOLDEX	1511	S	Human	25	1400.2**	9.1	3	26300
			StAH	25	498.4**	2.8	108	18200
MOLDEX	1512	M	Human	28	997.2	11.7	4	33400
			StAH	28	656.8	3.1	36	3460
MOLDEX	1513	L	Human	28	470.8	19.3	7	21000
			StAH	28	380.8	3.6	7	3600
SPERIAN	N1105	M/L	Human	28	7.9	3.3	2	199
			StAH	28	4.7	2.2	2	61
SPERIAN	N1105	S	Human	28	9.1	4.0	1	374
			StAH	28	8.7	3.5	2	737

*Number of test trials.

**GM FFs for the independent variable "Platform" are statistically different (*P*-value < 0.05) by ANOVA and by Duncan's Multiple Range Test.

Results (continued)

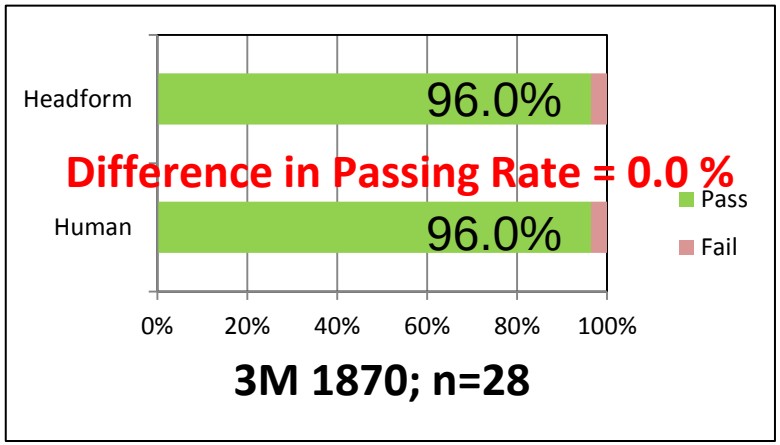


Correlation of "Overall" Test Exercise Geometric Mean Fit Factor (FF) for Human and Static Headform Testing.

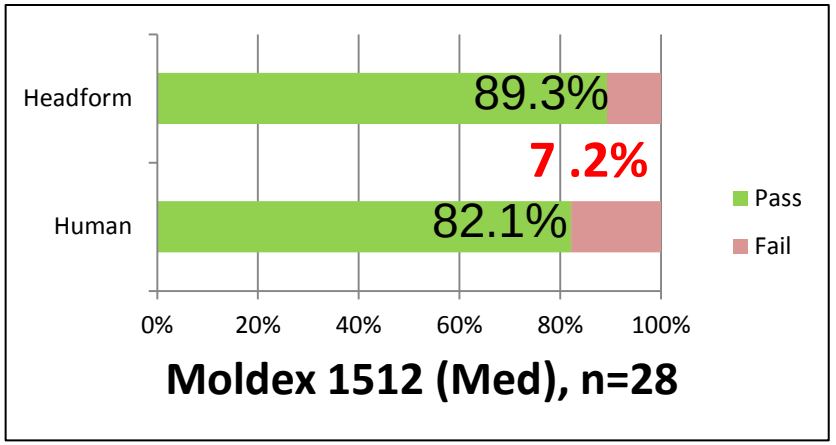
Note: *n* = 28 test for each model except for Moldex 1511 (*n* = 25).

Results (continued)

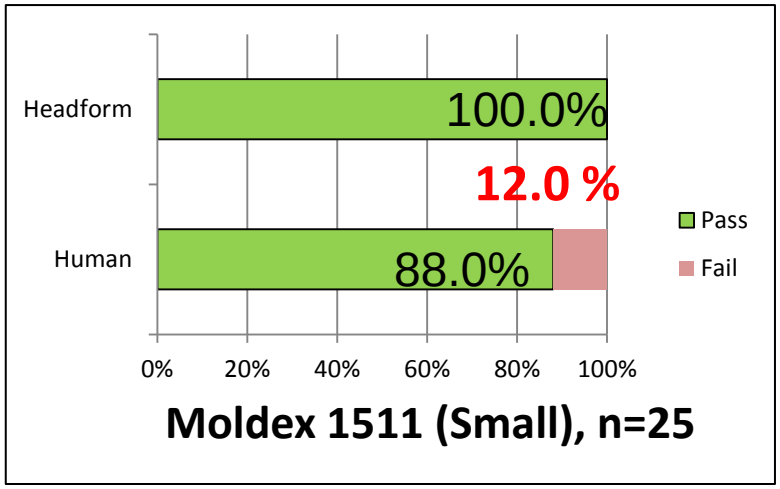
"Overall" Fit Factor Passing Rate



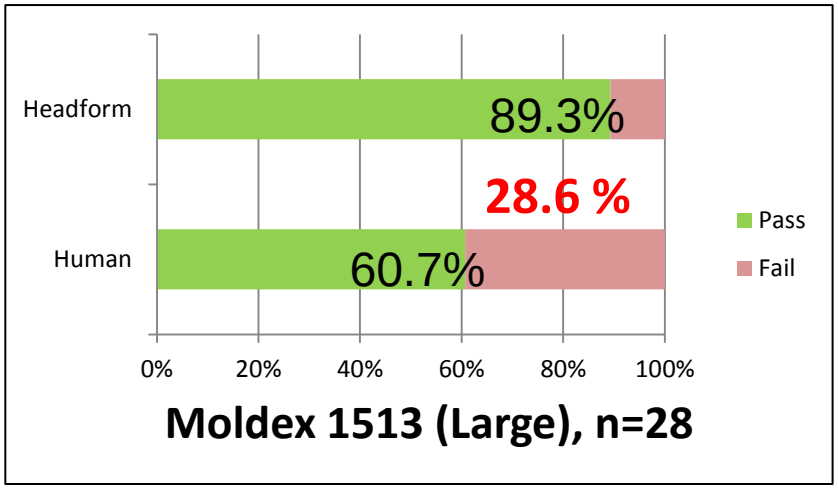
3M 1870; n=28



Moldex 1512 (Med), n=28



Moldex 1511 (Small), n=25

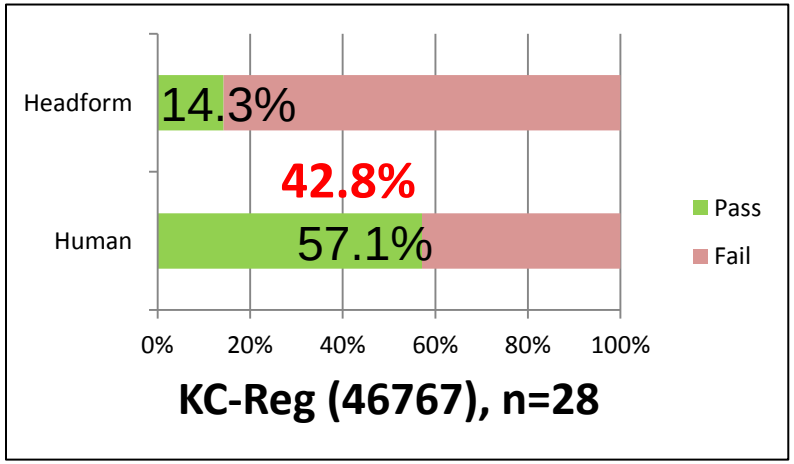


Moldex 1513 (Large), n=28

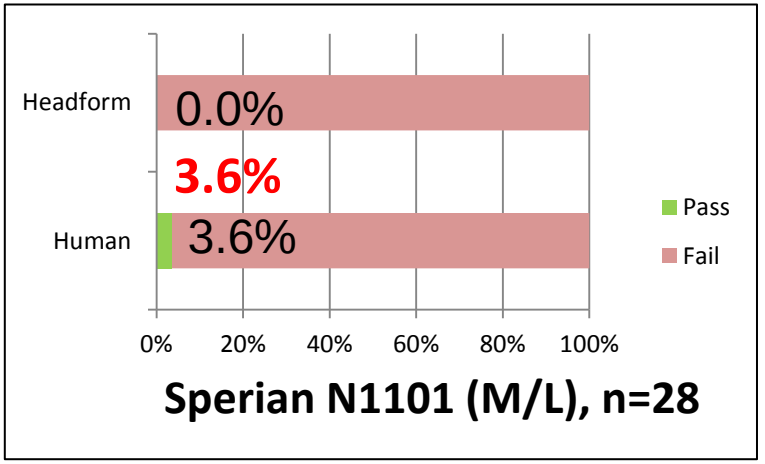
Passing criterion is "Overall" exercise Fit Factor ≥ 100.

Results (continued)

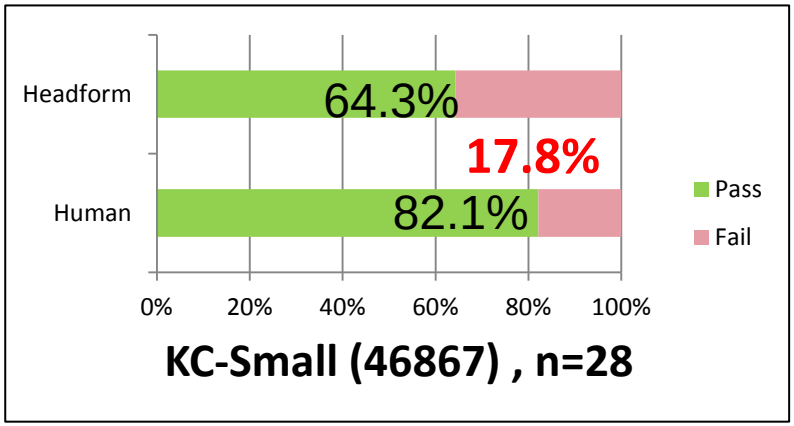
"Overall" Fit Factor Passing Rate



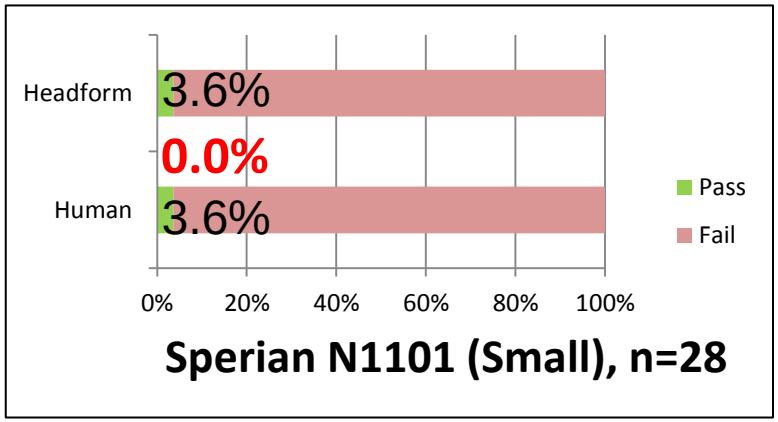
KC-Reg (46767), n=28



Sperian N1101 (M/L), n=28



KC-Small (46867) , n=28



Sperian N1101 (Small), n=28

Passing criterion is "Overall" exercise Fit Factor ≥ 100.

Conclusions and Recommendations

- **Preliminary results indicate the Static Advanced Headform demonstrates utility as a tool for assessing a range of fit provided by different N95 FFR models**
- **Further research is needed to determine the experimental factors that may influence the correlation of human and Advanced Headform fit factors (e.g., anthropometric dimensions of subjects, headform humidified exhaled breath, dynamic test exercises, etc.)**

Future Direction

Chatty Abel

Expressive Abel

Disclaimer: The respirators used in this study were randomly selected from those commercially available. The study was not done to determine respirator performance but to determine the fit measured on a headform correlates with the fit obtained by a person wearing the respirator. There are other models available (including from the same manufacturer) that were not tested . Due to the limited number of tests performed people should not generalize that any one respirator performs better than others in the same class based on the results of this study.

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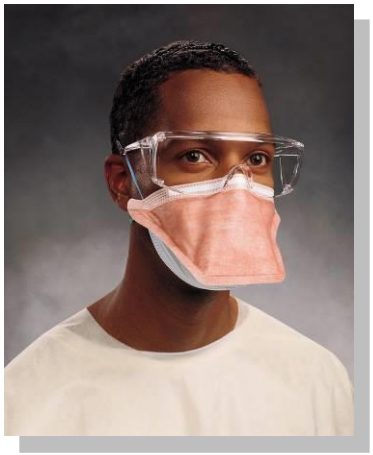

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Disclaimer:

The findings and conclusions in this presentation have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.

Thank you

Project Publications

- Bergman, Zhuang, Hanson, et al. *Development of an Advanced Respirator Fit Test Headform* (J. Occup. Environ. Hyg., In Press)
  - N95 FFR donnings on the medium size StAH showed much less leakage (i.e., resulted in better fit) compared to previous studies using older static headforms
  - The seven evaluated FFR models (which are expected to achieve FFs ≥ 100 on human subjects) achieved FFs ≥ 100 on the StAH

- He, Grinshpun, Reponen, et al. *Effect of Breathing Frequency on the Total Inward Leakage of an Elastomeric Half-Mask Donned on an Advanced Manikin Headform* (Submitted to Annal. Occup. Hyg., April 2013).
  - Various combustion aerosols, particle sizes, flowrates, and breathing rates were used to assess inward leakage (IL) of an elastomeric half-mask mounted on the StAH
  - The effect of breathing frequency on IL is less significant than the effects of aerosol type and breathing flow rate